



Outbreak Readiness & Response

CAPABILITY STATEMENT

Integrum Scientific, LLC, is an Outbreak Readiness and Response company founded to **reduce the impact of infectious disease outbreaks, especially in the most vulnerable regions of the world**. We provide a new paradigm for outbreak response and the conduct of clinical trials for medical countermeasures (MCMs). We provide a full-circle approach (highlighted below) for prevention, preparation, and response that includes **on-demand access to and training from a network of the world's leading infectious disease researchers, operations planned by global-leaders in international clinical research logistics, and customized mobile labs for providing the fastest way to test, treat, and collect biointelligence related to influenza and emerging infectious diseases in the hardest to reach areas of the world**.

We develop standardized and forward leaning solutions, including those services highlighted in the graphic below, to support the full cycle of infectious disease risk management: **surveillance, prevention, preparedness, and response**.



Prevention

- Clinical trials
- Classic and Adaptive study design
- Protocol Design, Project Management, Monitoring



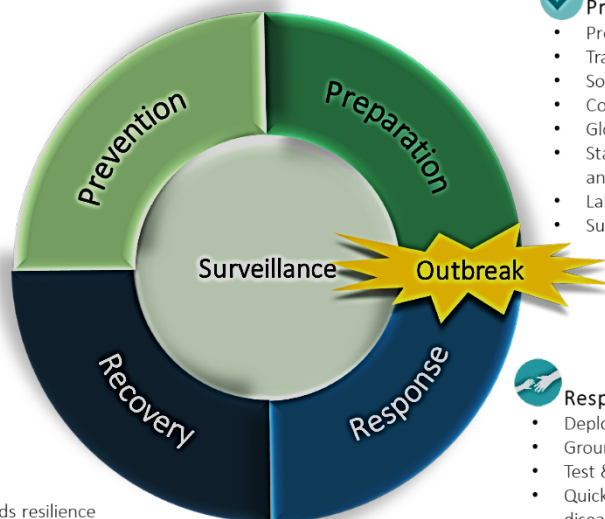
Surveillance

- Global surveillance through network of thought leaders and footprint in the ID hotspots
- Ground truth assessment
- Sample collection, biobanking & shipping



Recovery

- Support to survivor networks
- Legacy – Leave on good terms
- The best resource for the future that builds resilience



Preparation

- Pre-negotiated global agreements
- Training & Education
- Social & Anthropological Expertise
- Country-specific regulatory support
- Global Infrastructure Development
- Standardized protocols, study documents, and communication lines
- Lab assessments and strengthening
- Supply chain and logistics support



Response

- Deployment support
- Ground truth assessment
- Test & treat with mobile labs
- Quick mobilization of global infectious disease experts, & trained on-the-ground professionals
- Networked with NGOs & WHO

Our staff has over 20 years of experience in clinical research, including direct experience and deep relationships around the world working on landmark clinical trials and doing pivotal research in **South America, Africa, Southeast Asia, broader regions of Asia, including India and Russia, and the Middle East, specifically Israel**. We offer expertise in a wide range of infectious disease research, including

- Ebola
- chikungunya
- Zika
- Lassa fever
- Marburg
- MERS
- respiratory infections
- and diseases considered to be biothreats, such as anthrax, smallpox, plague, and tularemia

Our operations are backed by an **Infectious Disease Scientific Advisory Board (IDSAB)** composed of experts in clinical field research and the development and mobilization of specialty vehicles and equipment for remote clinical research and outbreak response. Our IDSAB is composed of current and former leaders from the US Army Medical Research Institute of Infectious Diseases (USAMRIID), the Bill & Melinda Gates Foundation Global Health Program Strategy Team, the Uganda Virus Research Institute (UVRI), the Infectious Disease Clinical Research Program of the Uniformed Services University (USU), and several global



leaders in academic research on infectious disease. The members of our IDSAB are trusted advisors on preparation for outbreak response mobilization within the greater biological threat community and have served on panels for organizations such as the Defense Threat Reduction Agency (DTRA), the World Health Organization (WHO), the National Academy of Medicine and the Biomedical Advanced Research and Development Authority (BARDA). Our IDSAB's global relationships provide immediate ground truth about emerging threats in infectious disease hotspots. Their ties with local governments allow us to prepare pre-negotiated global agreements and to lay the groundwork for country-specific regulatory support to improve our ability to mobilize quickly when an outbreak occurs.

We also provide **clinical trial support** for an advanced development pipeline for emerging infectious diseases and drug resistant strains of bacteria and viruses. Our services include:

- Protocol design support
- Project Management
- Clinical Monitoring with experienced, in-country Clinical Research Associates
- Clinical Site Preparation – including site feasibility assessments, site qualification visits, and study initiation visits to ensure sites start enrolling eligible subjects in a timely manner
- Subject recruitment and retention support – providing sites with the tools, training, and resources to support efficient recruitment and retention
- Infrastructure development support to reduce risk to study success
- Cold chain long term storage of product and cold chain storage



We customize **mobile labs** that enable the fastest way to test and treat on site in the hardest to reach areas of the world. These mobile laboratories combined with our global logistics capabilities enable access to patient populations in challenging environments where infectious diseases are most prevalent. Our mobile labs are configurable for **diagnostics or clinical trial support**. These rugged vehicles can travel off-road, run on the “dirty diesel” available overseas, and can be shipped on C130 cargo planes. These vehicles provide a BSL 3+ laboratory environment, Class II biosafety cabinets, and a pass box to reduce the risk of contamination. The mobile units have two independent power supply units with uninterrupted battery backup to provide deliberate redundancy. They also have their own source

of network connectivity for data management and real-time communications. We can customize the units to provide on-site diagnostic capabilities for known pathogens using BioFire® or GeneXpert® or experimental diagnostics using MinIon®. They also support standard care during an outbreak, providing routine chemistry, hematology, and blood products. The vehicles can also provide field ready clinical trial support, including diagnostics, cold chain storage for therapeutics (4C to -80C), document handling, test article or investigational material storage and preparation, sample preparation, and secure storage and bio-banking.

We also invest in establishing **long-term relationships in the communities where we work**. We train and educate clinical research staff both in the US and in communities worldwide to help protect and prepare those who will be on the front lines. We employ social and anthropological experts to ensure we are culturally sensitive to the norms of the communities where we work. Even after our operations conclude, we support survivor networks, providing training and job opportunities for those whose lives have been affected by the outbreaks. We do this not only as a humanitarian effort but in recognition that these relationships will enable a better positioning when we need to return.

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